

### **REMARKS/ARGUMENTS**

Applicant respectfully request reconsideration of this application.

By the amendments, Applicants do not acquiesce to the propriety of any of the Office's rejections and do not disclaim any subject matter to which Applicants are entitled. *Cf. Warner Jenkinson Co. v. Hilton-Davis Chem. Co.*, 41 U.S.P.Q.2d 1865 (U.S. 1997).

#### **In the Claims**

Claims 17-20 are pending in this application. Claims 1-16 and 21-50 have been previously canceled.

Claim 17 has been amended to recode that the tumor cell composition "consists of" the recited elements and that the tumor cell composition is irradiated. Support for the amendment can be found in the specification, for example on page 24, lines 13-14.

New claims 51 and 52 have been added. Claim 51 recited a process for making the tumor cell composition of claim 17 comprising the steps of infecting the tumor cells with a retrovirus vector encoding both B7-2 and an additional immune modulator, selecting the infected primary tumor cells for expression of B7-2 and the additional immune modulator; and irradiating the selected primary tumor cells expressing B7-2 and at least one additional immune modulator. Support for new claim 51 can be found on at least page 23, lines 13-25 and page 24, lines 13-14 of the specification.

New claim 51 is directed to one embodiment of the tumor cell composition and support can be found at at least page 23, lines 9-25 and page 24, lines 13-14 of the specification.

No new matter has been introduced as a result of the claim amendments.

#### **35 U.S.C. §102 Rejections**

The rejection of claims 17-20 under 35 USC §102(e) as being anticipated by U.S. Patent No. 6,548,068 to Schlom et al. (hereinafter "Schlom").

A claim is anticipated under 35 U.S.C. §102 only if each and every element as set forth in a claim is found, either expressly or inherently described, in a single prior art reference (MPEP §2131; *Verdegaal Bros. V. Union Oil Co. of California*, 814 F.2d, 628, 631, 2 USPQ2d 1051 (Fed. Cir. 1987)). A claimed invention is anticipated only when it is "known to the art in the detail of the claim." *Karsten Manufacturing Corp. v. Cleveland Golf Co.*, 242 F.3d 1376, 1383 (Fed. Cir. 2001). In other words, not only must the limitations of the claim be shown in a single prior art reference, the limitations must be "arranged as in the claim." *Id.*

1. The prior art

Schlom discloses a composition of recombinant viral vector vaccines for the prevention of treatment of cancer. Specifically Schlom discloses a composition of recombinant viral vectors comprising genes encoding an antigen(s) and recombinant viral vectors comprising a gene(s) encoding an immunostimulatory molecule(s). Schlom, column 5, lines 16-23. Schlom also discloses cancer cells which have been injected with the recombinant virus or combination of recombinant virus *in situ* or *in vitro* and that tumor cells "expressing both the tumor associated antigen along with an immunostimulatory molecule are administered to a mammal in an effective amount to result in tumor reduction or elimination in the mammal afflicted with a cancer." Schlom, column 13, line 64 to column 14, line 4.

2. The prior art does not disclose all the elements of the pending claims

a. Claim 17

Independent claim 17 recites "a tumor cell composition consisting of an isolated primary tumor cell modified to express a B7-2 proteins and at least one additional immune modulator, wherein said isolated primary tumor cell expressing B7-2 and at least one additional immune modulator has been irradiated."

Schlom does not disclose isolated primary tumor cells that have been modified to express B7-2 proteins and at least one additional immune modulator, wherein the isolated primary tumor cell expressing B7-2 and at least one additional immune

modulator has been irradiated. Therefore, Schlom does not disclose each and every element of claim 17 and claim 17 is not anticipated by Schlom.

b. Claims 18-20

Claims 18-20 are dependent on independent claim 17. Since Schlom does not disclose each and every element of claim 17, it necessarily follows that Schlom does not disclose the subject matter disclosed in dependent claims 18-20.

3. Schlom does not provide an enabling disclosure for the claimed invention

Even if Schlom disclosed each and every element of the pending claims, an Applicant respectfully asserts that it does not, Schlom is not enabling for isolated primary tumor cells that have been modified to express B7-2 proteins and at least one additional immune modulator, wherein the isolated primary tumor cell expressing B7-2 and at least one additional immune modulator.

A prior art publication must contain within its four corners a sufficient description to enable such a person to make the invention without an unreasonable amount of experimentation (*Advanced Display Systems Inc. v. Kent State University*, 212 F.3d 1272, 1282, 54 USPQ2d 1673, 1679 (Fed. Cir. 2000), cert. denied, 532 U.S. 904 (2001)). Furthermore, in *Dewey & Almy Chem. Co. v. Mimex Co.* (124 F.2d 986, 990, 52 USPQ 138 (2d Cir. 1942)), Judge Learned Hand emphasized the point:

No doctrine of the patent law is better established than that a prior patent or other publication to be an anticipation must bear within its four corners adequate directions for the practice of the patent invalidated. If the earlier disclosure offers no more than a starting point for further experiments, if its teaching will sometimes succeed and sometimes fail if it does not inform the art without more how to practice the new invention, it has not correspondingly enriched the store of common knowledge and it is not an anticipation."

Schlom discloses as an alternative embodiment, cancer cells which have been injected with the recombinant virus or combination of recombinant virus *in situ* or *in vitro* and that tumor cells "expressing both the tumor associated antigen along with an immunostimulatory molecule are administered to a mammal in an effective amount to

result in tumor reduction or elimination in the mammal afflicted with a cancer." Schlom, column 13, line 64 to column 14, line 4. Schlom does not provide any specific examples of such tumor cells containing these components or of their use as immunogenic compositions. The disclosure of Schlom merely provides a starting point for further experiments and therefore is not an anticipation of the claimed subject matter. *see also Takeda Chemical Industries, Ltd. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350, 1359-1360, 83 USPQ.2d 1169, 1177-1179 (Fed. Cir. 2007) (the cited art must disclose predictable solutions for the problem at hand and not a broad (not "finite") array of solutions that could be selected.)

Therefore, in light of the arguments presented *supra*, Applicant respectfully asserts that claims 17-20 and new claims 50-51 are novel and not anticipated by Schlom and requests the withdrawal of the rejection on this basis.

### CONCLUSION

For the foregoing reasons, Applicant believes all the pending claims are in condition for allowance and should be passed to issue and therefore Applicant respectfully requests that a timely Notice of Allowance be issued in this case.

The Commissioner is authorized to charge any fee which may be required in connection with this Amendment to deposit account No. 50-3207.

Respectfully submitted,

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